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| APPLICATION NO.             | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|------------------------------|------------------|
| 10/582,304                  | 04/20/2007  | Naoki Kimura         | I4875-166US1<br>CI-A0323P-US | 4817             |
| 26161                       | 7590        | 10/14/2010           |                              | EXAMINER         |
| FISH & RICHARDSON P.C. (BO) |             |                      |                              | GUSSOV, ANNE     |
| P.O. BOX 1022               |             |                      | ART UNIT                     | PAPER NUMBER     |
| MINNEAPOLIS, MN 55440-1022  |             |                      | 1643                         |                  |
|                             |             |                      | NOTIFICATION DATE            | DELIVERY MODE    |
|                             |             |                      | 10/14/2010                   | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

|                              |                                      |                                      |
|------------------------------|--------------------------------------|--------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/582,304 | <b>Applicant(s)</b><br>KIMURA ET AL. |
|                              | <b>Examiner</b><br>ANNE M. GUSSOW    | <b>Art Unit</b><br>1643              |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 26 July 2010.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1-10,17-24 and 29-46 is/are pending in the application.

4a) Of the above claim(s) 17-21,29-31 and 35-46 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1 and 22-24 is/are rejected.

7) Claim(s) 2-10 and 32-34 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/26/10, 9/21/10

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claim 4 has been amended.

Claims 11-16 and 25-28 have been cancelled.

Claims 17-21, 29-31, and 35-46 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 16, 2008.

2. Claims 1-10, 22-24, and 32-34 are under examination.

3. The following office action contains NEW GROUNDS of Rejection.

***Information Disclosure Statement***

4. The information disclosure statements (IDS) submitted on July 26, 2010 and September 21, 2010 were filed after the mailing date of the non-final office action on March 24, 2010. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner and an initialed copy of the IDS is included with the mailing of this office action.

***Rejections Withdrawn***

5. The rejection of claims 1-10, 22-24, and 32-34 under 35 U.S.C. 103(a) as being obvious over Ozaki, et al. in view of Beresford, et al. as evidenced by the specification is withdrawn in view of applicant's arguments regarding the availability of the 2D7 antibody.

***NEW GROUNDS of Rejection***

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1 and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Tawara, et al. (US PAT 7,262,278, national stage filing date August 29, 2003).

The claims recite an antibody comprising two heavy chain variable regions and two light chain variable regions, wherein the antibody is a single chain polypeptide having a binding activity against human leukocyte antigen (HLA). A pharmaceutical composition comprising the antibody of claim 1 as an active ingredient, wherein the antibody has cell death inducing activity against B cells or T cells, wherein the B cells or T cells are activated B cells or activated T cells.

Tawara, et al. teach single chain antibodies that bind to human leukocyte antigen (HLA). Tawara, et al. teach the antibodies may be sc(Fv)2 formats. Tawara, et al. teach the antibodies in pharmaceutical compositions. The limitations of claims 23 and 24 are inherent properties of an antibody. Since the antibody would bind to an antigen on a B cell or T cell, the antibody would necessarily have a cell death inducing activity against those cells. Since the claims do not define the specific antibody that binds to HLA, and Tawara, et al. teach single chain antibodies that bind to human leukocyte antigen in a pharmaceutical composition, all the limitations of the claims have been met.

### ***Conclusion***

8. Claims 1 and 22-24 are rejected.

Claims 2-10 and 32-34 are objected to as being dependent upon a rejected base claim.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow  
October 10, 2010

/Anne M. Gussow/  
Examiner, Art Unit 1643